

Advice for Patients

With Cochlear Implants: New Information on Meningitis Risk

February 6, 2006

This advice for patients gives the latest information on the risk of bacterial meningitis in children with cochlear implants and recommends steps to reduce the risk.

Previous Information

A study published in 2003 (NewEngJMed, 349.5: 435-445) (<http://content.nejm.org/cgi/content/full/349/5/435>) by FDA and the Centers for Disease Control and Prevention (CDC) followed children with cochlear implants for two years after the device was implanted. The study showed that children whose implants have a positioner get bacterial meningitis more often than children with implants that don't have positioners or children without implants. A positioner is a small rubber wedge that helps the physician position the implant during surgery. Bacterial meningitis, a serious infection in the cerebrospinal fluid (CSF) around the brain and spinal cord, can be fatal. Only Advanced Bionics Corporation sold an implant that had a positioner, and none were implanted after July 2002.

New Information

Now a new study (Pediatrics February 2006), which followed the children for two more years, has found that the increased risk for meningitis persists beyond two years after implantation. This study highlights the importance of continuing to monitor children with cochlear implants for signs of middle ear infection and meningitis. Children need to be monitored for as long as the implant is in place.

Recommendations

- Continue close monitoring for meningitis and middle ear infections for all children with a cochlear implant, but particularly for children whose implants have a positioner. Consult your implanting doctor to determine if the patient has a positioner. **It is, however, important to monitor all cochlear implant patients.**
- Check the patient's record of vaccinations against CDC's recommendations (www.cdc.gov/nip/issues/cochlear/cochlear-gen.htm), which show what vaccines cochlear implant patients should receive and when the vaccines should be given. The CDC Immunization Center telephone number is 800-232-4636. The TTY number is 888-232-6348.

- Contact your doctor immediately if the patient has any symptoms of meningitis or middle ear infection. These may include:
 - high fever
 - headache
 - stiff neck
 - nausea
 - vomiting
 - irritability
 - discomfort looking into bright lights
 - sleepiness or tiredness
 - confusion
 - ear pain
 - hearing loss
 - appetite loss
- Follow your doctor's prescription for antibiotics very carefully. It is very important that you make sure the patient takes the antibiotic as often as prescribed and for as long as prescribed, so it can work properly.

Additional Background Information

The original CDC/FDA study reviewed the medical records of 4,264 children under the age of six at the time of implantation. The study was undertaken because of increased concern about the risk of meningitis associated with cochlear implants. The study focused on young children because they account for most known meningitis cases, and they represent the population that now receives a large proportion of cochlear implants

In the original study, 26 of the 4,264 children developed meningitis during the first 24 months after implantation. Children who had cochlear implants with electrode positioners developed meningitis more often than children who had implants without positioners. The study was unable to determine how the positioner increased the risk for developing meningitis. Because the number of meningitis cases in the original study was small, it is hard to predict the risk of developing meningitis with various cochlear implant models.

The new study followed children from the original study for an additional two years. Six children with positioners developed meningitis after two years. Of these six, three developed meningitis between three and four years after implantation. Children in the study without a positioner did not develop meningitis, but this group of children was so small it is hard to predict the risk of their developing meningitis. The study also concluded there is not enough information now to recommend surgical removal of devices with a positioner.

Information for health care providers appears on the web at <http://www.fda.gov/cdrh/safety/020606-cochlear.html>.

For general information on cochlear implants visit: <http://www.fda.gov/cdrh/cochlear/>